

1 OLIVER B. MITCHELL III  
2 PO BOX 1705  
3 LONG BEACH, CALIFORNIA 90801  
4 PH: (562) 719-3872  
5 FAX: (888) 829-7124  
6 REDPATCHMARINE@HOTMAIL.COM  
7 IN PRO PER



5 LACV1903607-R-ASx

6 UNITED STATES DISTRICT COURT

7 FOR THE CENTRAL DISTRICT COURT OF CALIFORNIA

8 OLIVER B. MITCHELL III,  
9 Plaintiff,

10 vs.

11 GRIFOLS USA, LLC.,  
12 Defendant.

13 CASE NUMBER \_\_\_\_\_

14 COMPLAINT FOR INJUNCTIVE RELIEF

15 **COMPLAINT FOR INJUNCTIVE RELIEF**

16 **INTRODUCTION**

17 1. This is an action under the Freedom of Information Act ("FOIA") seeking the release  
18 of clinical records relating to the Plaintiff participation in plasma donations and Grifols Plasma  
19 policy to withhold documents otherwise subject to a Freedom of Information Act request for reasons  
20 outside the statutory exemptions.

21 2. Plaintiff, Oliver B. Mitchell III, sought access to records related to his plasma  
22 donations at Grifols Plasma 19255 Vanowen Street Reseda, California 91335. This case concerns  
23 documents that Mr. Mitchell identified as responsive but Grifols Plasma failed to disclose, thus,  
24 prompting this litigation. Because this justification for denial does not fall within one of the  
25 statutorily designated exemptions to the FOIA, Defendants improperly withheld clinical records from  
26 Mr. Mitchell.

27 3. Clinical Trials are "experiments" or observations done in clinical research. Such

1 prospective “biomedical” or “behavioral” research studies on human participants are designed to  
2 answer specific questions about biomedical or behavioral interventions. Grifols Plasma “produces  
3 and markets life-saving, plasma derived medicines, diagnostic systems and hospital pharmacy  
4 products that are used to treat patients in more than 100 countries worldwide.”

5 4. On February 26, 2019, Mr. Mitchell first began to request documents under the FOIA  
6 from Defendants Grifols USA, LLC and Grifols Plasma. To date, the Plaintiff has not received the  
7 documents as indicated in his request.

8 5. The Plaintiff is legally entitled to these documents, which were requested over thirty  
9 days ago. Grifols Plasma and Grifols USA, LLC., has far exceeded the statutory and regulatory time  
10 limitation to respond to the Plaintiff's request.

11 6. Given the seriousness of the violations at hand, it is of concern that the requested  
12 documents are disclosed to the Plaintiff. Accordingly, this Court should order Defendants to provide  
13 the requested records to Mr. Mitchell immediately.

#### 15 JURISDICTION & VENUE

16 7. This Court has subject matter jurisdiction over this action and personal jurisdiction  
17 over the parties pursuant to 5 U.S.C. § 552(a)(4)(B) and 5 U.S.C. § 552(a)(4)(A)(vii). This Court also  
18 has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701–706.

19 8. Because Defendant failed to comply with the requirements to respond set forth in 5  
20 U.S.C. § 552(a)(6)(A), Plaintiffs have constructively exhausted their administrative remedies and are  
21 entitled to proceed with this judicial action pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

22 9. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B) because Defendants  
23 principal place of business is in California.

#### 24 PARTIES

25 10. Plaintiff, Oliver B. Mitchell III, is a resident of Los Angeles, California.

26 11. Defendant, Grifols Plasma and Grifols USA, LLC., “produces and markets life-saving,  
27 plasma derived medicines, diagnostic systems and hospital pharmacy products that are used to treat

1 patients in more than 100 countries worldwide."

2  
3 **STATEMENT OF FACTS**

4 12. As the United States Supreme Court has recognized, "the basic purpose of the FOIA is  
5 to open agency action to the light of public scrutiny." Department of Air Force v. Rose, 425 U.S. 352,  
6 372 (1976).

7 13. On February 26, 2019, the Plaintiff filed a FOIA request with Grifols Plasma seeking  
8 records relating to his plasma donations located at 19255 Vanowen Street Reseda, California 91335.  
9 Per the FOIA request "Dear Grifols, ...In responding please provide the following: 1) Copies of all  
10 health and billing records, 2) Copies of all records and notes within the patient's medical/research  
11 file." **EXHIBIT 1**

12  
13 **CAUSES OF ACTION**

14 14. The Plaintiff repeats and realleges paragraphs 1 -13.

15 15. Defendants failure to timely respond to the Plaintiffs request violates the FOIA, 5  
16 U.S.C. § 552(a)(6)(A)(ii), and the California Public Records Act 6250 et seq.

17 16. Defendants' failure to make a reasonable effort to search for records responsive to the  
18 Plaintiffs request violates the FOIA, 5 U.S.C. § 552(a)(3)(C), and the California Public Records Act  
19 6250 et seq.

20 17. Defendants' wrongful withholding of non-exempt responsive materials violates the  
21 FOIA, 5 U.S.C. § 552(a)(3)(A).

22  
23 **PRAYER FOR RELIEF**

24 WHEREFORE, Plaintiff respectfully request that this Court enter a judgment for Plaintiff and  
25 award the following relief:

26 a. Order Defendant, by a date certain, to conduct a search that is reasonably likely to lead  
27 to the discovery of any and all records responsive to Plaintiffs' February 26 and March 25 Requests;  
28 b. Order Defendant, by a date certain, to demonstrate that it has conducted an adequate  
search;

1                   c.     Order Defendant, by a date certain, to produce to Plaintiffs any and all nonexempt  
2 records or portions of records responsive to Plaintiffs' February 26 and March 25 Requests, as well as  
3 a Vaughn index of any records or portions of records withheld due to a claim of exemption;  
4  
5                   d.     Enjoin Defendant from withholding the requested records;  
6  
7                   e.     Enjoin Defendants from charging Plaintiff fees for the processing of their request;  
8  
9                   f.     Award Plaintiff its costs and attorney's fees reasonably incurred in this action,  
10 pursuant to 5 U.S.C. § 552(a)(4)(E); and  
11  
12                   g.     Grant Plaintiffs such other and further relief as the Court may deem just and proper.

13  
14                   Respectfully submitted this 29<sup>th</sup> day of April 2019.



15                   Oliver B. Mitchell III (Pro Se)  
16  
17                   PO Box 1705  
18  
19                   Long Beach, CA  
20  
21                   90801  
22  
23                   Tel: (562) 719-3872  
24  
25                   Fax: (888) 829-7124  
26  
27                   redpatchmarine@hotmail.com  
28

**OLIVER B. MITCHELL III**

**VS**

**GRIFOLS USA, LLC.,**

**EXHIBIT**

**1**

## Fax Message Transmission Result to +1 (323) 3431806 - Sent

RingCentral <service@ringcentral.com>

Wed 2/27/2019 2:12 PM

To: Oliver Mitchell <redpatchmarine@hotmail.com>

Here are the results of the 3-page fax you sent from your phone number (888) 829-7124:

Name	Phone Number	Date and Time	Result
	+1 (323) 3431806	Wednesday, February 27, 2019 at 02:12 PM	Sent

*Your fax(es) included the following file(s), which were rendered into fax format for transmission:*

File Name	Result
GRIFOLS PLASMA FOIA REQUEST.docx	Success

Oliver Bruce Mitchell III  
PO Box 1705  
Long Beach, California  
90801

February 26, 2019

SENT VIA FAX AND USPS MAIL

**Grifols USA, LLC**  
**2410 Lillyvale Avenue**  
**Los Angeles, California**  
**90032**  
**Ph (888) 474-3657**  
**Fax (323) 343-1806**

**Grifols Plasma**  
**19255 Vanowen Street**  
**Reseda, California**  
**91335**  
**Ph (818) 201-3800**

Subj: HIPAA Privacy Authorization Form

Dear Grifols,

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.

Grifols Plasma “produces and markets life-saving, plasma-derived medicines, diagnostic systems and hospital pharmacy products that are used to treat patients in more than 100 countries worldwide.”

Clinical research ethics are the set of relevant ethics considered in the conduct of a clinical trial in the field of clinical research. It borrows from the broader fields of research ethics and medical ethics.

Return of results is a concept in research ethics which describes the extent of the duty of a researcher to reveal and explain the results of research to a research participant. Return of results is particularly discussed in the field of biobanks, where a typical case would be that many members of a community donate biobank specimens for medical research. In the course of the research, especially in human genomics research, scientists may discover personal health information which could influence the behavior of specimen donors if they had this information.

In accordance with the 21<sup>st</sup> Century Cures Act, the California Public Records Act 6250 et seq., and the Health Insurance Portability and Accountability Act (HIPPA), 45 C.F.R. Parts 160 and 164, I am requesting copies of all records pertaining to my donations at Grifols Plasma located at 19255 Vanowen Street, Reseda, CA 91335.

If there are any fees for searching or copying these records, please inform me of the cost if it will exceed \$5.00. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in my best interest and will contribute significantly to my understanding of your clinical research. This information is not being sought for commercial purposes.

In responding please provide the following:

1. Copies of all health and billing records.
2. Copies of all records and notes within the patients' medical/research file.

The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with a written explanation about when I might expect copies of the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

In order to access the appropriate files the patients name and last four are provided: Oliver B. Mitchell III 3512.

Please mail all records to the above address.

Thank you for considering my request.

Sincerely,

X

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Oliver B. Mitchell III